DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Bennett & Company
Attention: Martha M. Bennett
4140 Bison Boulevard
Lake Havasu City, AZ 86404

APR 12 2002

Docket No. 01P-0351/CP1

Dear Ms. Bennett:

This is in response to your petition filed on August 13, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Sodium Tetradecyl Sulfate Injection, 0.2% and 0.5%. The listed drug products to which you refer in your petition are Sotradecol® (Sodium Tetradecyl Sulfate) Injection, 1% and 3%, approved under NDA 05-970, held by Elkins Sinn.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) of the Act, such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug products with strengths that differ from the listed drug product.

Your request involves changes in strength from that of the listed drug products (i.e., from 1% and 3% to 0.2%, and 0.5%). The changes that you request are the type of changes that are authorized under Section 505(j)(2)(C) of the Act. The Agency has determined that your proposed changes in strength raise questions of safety and effectiveness, and has concluded that clinical trials are required for these specific drug products. Specifically, you are seeking a new lower dose that is not supported by the approved labeling. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug products.

In addition, your request involves a new indication (i.e., treatment of minor venules and spider veins (venous flares)) as indicated in your proposed labeling. This change is not the type that is authorized under Section 505(j)(2)(C) of the Act. Therefore, FDA is denying this portion of the petition because Section 505(j) permits such petitions to seek variations in active ingredient, dosage form, or strength from that of the listed drug and does not authorize petitions for indications that differ from the listed drug. Please contact the Division of Dermatologic and Dental Drug Products at (301) 827-2021 should you wish to pursue approval of this application under Section 505(b) of the Act.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

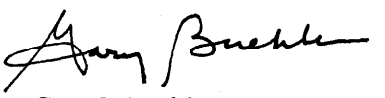
01P-0351

RDN1

For future reference, when submitting a 505(j)(2)(C) petition (ANDA Suitability Petition) that relies on a drug that is no longer marketed, the ANDA Suitability Petition must be accompanied by a separate petition seeking a determination from the Agency whether the listed drug was withdrawn for safety or effectiveness reasons (21 CFR § 314.122).

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research